

ORIGINAL
IN THE UNITED STATES
COURT OF FEDERAL CLAIMS
(BID PROTEST)

FILED
FEB 5 2016
U.S. COURT OF
FEDERAL CLAIMS

MANUS MEDICAL, LLC

Plaintiff,

v.

THE UNITED STATES,

Defendant.

CoFC No. 16-183 C

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

COMES NOW, Plaintiff Manus Medical, LLC (“Manus”), by and through undersigned counsel, and seeks injunctive and declaratory relief against the Department of Veterans Affairs (the “Agency,” the “Contracting Officer,” or the “VA”) pursuant to 28 U.S.C. § 1491(b)(1), Fed. R. Civ. P. 65, and Rule 65 of the Rules of the United States Court of Federal Claims (“CoFC R.”). By this action Manus seeks to enjoin the VA from going forward with award of a contract or contracts under the Solicitation No. VA240C-15-R-0022 (the “Solicitation,” “Request for Proposals,” or “RFP”), as written for the supply of Custom Sterile Procedure Packs.¹ The Solicitation as issued violates federal procurement law and regulation because it is a full and open competition and not set aside for small business participation. Furthermore, the terms of the Solicitation are defective because they provide an unfair advantage to a class of offerors called Medical Surgical Prime Vendors (“MSPVs”) via the improper bundling of requirements, and the

¹ According to the RFP Custom Sterile Procedure Packs are pre-packaged, sterilized sets of medical equipment and supplies identified by VA medical facilities from an identified packing and supply list. See RFP at 10.

procurement creates an organizational conflict of interest on the part offerors who are MSPVs. Additionally, Manus protests its recent exclusion from the competitive range in this procurement.

PARTIES

1. Plaintiff, Manus, is a Virginia corporation whose principal office is located at 3420 Pump Rd., Suite 348, Richmond, VA 23233.
2. The Defendant is the United States of America acting through the VA.

JURISDICTION AND STANDING

3. Jurisdiction in this Court is based on the Tucker Act, 28 U.S.C. § 1491.
4. Manus has standing as an interested party to bring this action since Manus is an actual bidder under the VA's Solicitation whose economic interests are directly affected by the VA's defective RFP terms and Manus's exclusion from the competitive range.

BASIS OF THE PROTEST

A. The Terms of the Solicitation

5. The VA issued the Solicitation on or about August 3, 2015 seeking procurement of the following:

Provide for a Custom Sterile Procedure Pack Program for the production and delivery of individualized custom procedure packs to be utilized by each of the estimated 44 medical centers within the SAO Central Region. The Custom Sterile Procedure Pack Program will include, but not limited to; pack assembly/manufacture, sterilization, quality assurance, and packaging, contractor electronic communication ordering reporting, and delivery. Orders for this program will be comprised of combining items from the schedule of items which includes two parts; the Component catalog (Schedule of Items Part A) and a Configuration/Non-Component list (Schedule of Items Part B) will be utilized for configuration for orders requested from each participated medical center in Attachment 4. All aspects of pack assembly, packaging and sterilization must adhere to the quality control standards set by the FDA.

RFP, § II at 10.

6. The RFP describes the Custom Sterile Procedure Pack Program as, “Custom pack programs are designed to develop individualized procedure packs to save on operating room start-up times, cut down on the time between patients, and generally create standard practices that result in hospital effectiveness, efficiency and charge/cost capture.” RFP, § I at 9.

7. The stated intent of the RFP is to procure pre-packaged medical supplies for use by VA facilities in the Central United States. The contents of the packs are supposedly listed in a catalogues of supplies called the “Schedule of Items.” As will be seen this alleged model process is belied by other portions of the RFP.

8. The RFP identifies Medical Surgical Prime Vendors as follows:

MSPV is the VAs primary means of medical and surgical supply distribution. The VA facilities realize a number of benefits from utilizing a single ordering and distribution prime vendor, including reduced administrative burden, inventory cost, and ordering efficiency. The current MSPV vendors for the Central Region VA Medical Facilities are Cardinal Health and Kreisers.²

RFP, § I at 10.

9. The role of the MSPVs is further described as, “The packs shall be available for distribution by the Medical Surgical Prime Vendor (**MSPV**) or by direct purchase, at the discretion of the local facility.” RFP, § III at 12 (emphasis in original).

10. The operation of the MSPVs are further described by the VA as follows:

Medical Centers pay prime vendors a distribution fee plus the product price. Product prices are primarily established by the Federal Supply Schedule Program (FSS), VA National Standardization Program, Veterans Integrated Service Network (VISN) and/or local contracts. The distribution fee is a markup to the product prices and is

² SAO Central encompasses Veterans Integrated Service Networks 9, 10, 11, 12, 15, 16 & 23. Kreisers is the MSPV for VISN 23. Cardinal Health 200 is the MSPV for VISNs 9, 10, 11, 12, 15 & 16. See <http://www.va.gov/oal/business/nc/mspv.asp>.

intended to cover prime vendor costs for managing customer inventories, ensuring the timely delivery of needed products to customers in a more efficient and effective manner than other conventional ordering methods, and administering electronic commerce systems in support of the program.

See <http://www.va.gov/oal/business/nc/mspv.asp>

11. Although the RFP describes the pack ordering process as follows:

Upon validation of pack configuration of components from Schedule of Items Part A (catalog) with Schedule of Items Part B (Configuration) and after approval of any required first article testing, a delivery order will be issued to initiate pack manufacture and delivery. A separate delivery order for the initial transition custom pack orders and for each subsequent order will be provided to the contractor for each participating facility.

RFP, § V at 13, in reality the actual ordering process is quite different.

12. As the RFP earlier states:

The Contractor shall have a clear implementation and transition plan that addresses the unique requirements of each facility served. The plan shall include a project management plan with specific goals and a schedule of significant milestones.

A. Implementation Plan.

The contractor shall submit a plan to the Contracting Officer outlining how it intends to implement the Custom Sterile Procedure Pack program at each of the medical facilities listed under the contract within 30 calendar days after receipt of award notification. The Contracting Officer shall approve, conditionally approve, or disapprove the plan within 10 calendar days. If the initial plan is disapproved, the contractor shall provide corrected plans, using the same time period above, until approved by the Contracting Officer.

(1) Due to the size and complexity of this requirement, during the implementation period, the contractor shall validate with each site pack configuration to ensure compliance with the individual facility specifications.

Validation with each site shall consist of, but not be limited to the following tasks:

- Facilitation of a meeting with facilities to develop packs.
- Configuration of components from Schedule of Items Part A (Catalog) with Schedule of Items Part B (Configuration).

- Production of First Article Packs shall be required at the request of the participating facilities. The disposal of the first article pack shall be the responsibility of the contractor.
- Delivery of first articles for testing and approval. Production of approved packs upon issuance of delivery order, in accordance with individual facility requirements.

RFP, § IV at 12 (emphasis added).

13. Clearly, this section means that the final configuration of the packs is subject to change based on meetings with the individual facilities, in which case first article packs may be required.

14. Problematically, one of the two MSPVs serving SAO Central is Cardinal Health 200, LLC, a firm that is also the incumbent supplier of Custom Packs to VA medical facilities within Veterans Integrated Service Network 12 under a contract award by the SAO-Central contracting office. See RFP, § I at 10. 14. Moreover, Cardinal Health 200 is identified as an interested vendor who intends on submitting an offer in response to the RFP.

15. Similarly, the other MSPV serving SAO Central is Kreisers, Inc. In January 2016 the VA authorized a sole-source Blanket Purchase Agreement to Kreisers to supply all Custom Pack requirements to the portion of SAO Central comprised of Veteran's Integrated Service Network (VISN) 23, which includes the VA's Medical Facilities located in Minneapolis, MN, Sioux Falls, SD, St. Cloud, MN, Fargo, ND, Omaha, NE, Iowa City, IA and Des Moines, IA pending an award of the SAO Central procurement. The term of this BPA is three months and is therefore not being challenged in this protest. The VA clearly has indicated a preference for procuring Custom Packs through existing MSPVs in making this sole source award.

16. Cardinal Health's and Kreiser's interest in this procurement is problematic because, by virtue of their standing as the MSPV serving SAO Central, they possesses intimate knowledge of both the user requirements at individual Medical Centers ("VAMCs") within SAO Central, it

also possesses intimate knowledge of the unique contents and pricing of existing competitor surgical packs.

17. Given the vast variability pack content from one VAMC to another, as left open by the Implementation Plan described above, the value of that unique knowledge is enormous. By virtue of their distribution of all surgical packs through the MSPV program, Cardinal Health and Kreisers, each know how to replicate the existing packs currently being acquired by each of the forty-four VAMCs within SAO Central.

18. This means that Cardinal and Kreisers face none of the expense and uncertainty associated with the Implementation Plan or the requirement to submit future First Article packs because they simply have to replicate the Customs Pack they currently distribute on behalf to VAMCs within SAO Central for incumbent suppliers such as Manus. Additionally, Cardinal Health and Kreisers, by virtue of their status as the VA's agent for distribution of vast quantity of medical supplies, knows what each offeror currently supplies to the VAMCs in their packs, where each offeror obtains their components from, and how the components are priced by each supplier. Obviously, this is an immense advantage.

19. Finally, it is well established that Cardinal Health, in its role as a MSPV, routinely charges suppliers of medical products a variety of fees when distributing their products through the MSPV program. Examples of such fees charged by Cardinal Health include distribution fees of up to 5% of the value of sales through the MSPV program, tracing report fees of up to 1.5% of such sales, and administrative fees of up to 1.5% of sales.³

³ Upon information and belief Kreisers does not charge suppliers such distribution fees and looks exclusively to the VA for remuneration of distribution fees.

20. It would be unconscionable for the VA to permit Cardinal Health or Kreisers to participate in this procurement as prospective suppliers where both firms are already engaged as a distribution agent to the VAMCs to be serviced under the procurement or where Cardinal Health is able to accord itself a significant price advantage versus the other prospective suppliers in the form of MSPV fees. Yet that is precisely what VA SAO Central is proposing to do on this procurement.⁴

21. A further inherent problem with the Solicitation as written is that it improperly bundles together requirements benefitting large offerors like the MSPVs. The requirements under the Solicitation are the same as those outlined under the Veterans Integrated Service Network (“VISN”) 19 procurement for Custom Surgical Packs which was conducted in 2013 as a set-aside for SDVOSB concerns. Not only did more than two responsible SDVOSB concerns submit responsive offers for the VISN 19 requirements, but the VA received multiple technically acceptable offers from SDVOSB concerns which resulted in an award to an SDVOSB at a fair market price.

22. Because the supplies sought under the RFP were previously furnished to the government on an individual basis across each VISN, the VA cannot justify its election to consolidate or “bundle” the requirements for all of the VISNs into one larger contract vehicle. The Small Business Administration (“SBA”) regulations provide that:

⁴ In response to questions addressing the unfair advantage that would accrue to an MSPV through its ability to charge fees to the other bidders, SAO Central simply replied that MSPV program was in the process of being re-competed and that the new procurement would forbid Cardinal Health or any other MSPV from charging such fees. This position is partially consistent with the pending VA procurement in that the current MSPV RFP states that future MSPVs will not be able to charge suppliers distribution fees. But there is no assurance that a new MSPV procurement will be awarded or in place in time to support this procurement which, by its own terms, contemplates delivery through current MSPVs Kreisers or Cardinal Health.

(e) *Contract bundling, bundled requirement, bundled contract, or bundling* means the consolidation of two or more procurement requirements for goods or services previously provide or performed under separate smaller contracts into a solicitation of offers for a single contract or a Multiple Award Contract that is likely to be unsuitable for award to a small business concern (but may be suitable for award to a small business with a Small Business Teaming Arrangement) due to:

- (1) The diversity, size, or specialized nature of the elements of the performance specified;
- (2) The aggregate dollar value of the anticipated award;
- (3) The geographical dispersion of the contract performance sites;
- (4) Any combination of the factors described in the paragraphs (e)(1), (2), and (3) of this section.

See 13 C.F.R. § 125.1(e).

23. Clearly, because of the identified benefits to the MSPVs bidding on this procurement bundling the requirements for the VISNs unduly restricts competition beyond what is reasonably necessary to satisfy the VA's needs.

B. The Procurement is not Set-Aside for Small Businesses

24. The Solicitation contemplates a single award indefinite delivery requirements contract for one contractor to provide a comprehensive Custom Sterile Procedure Pack Program which shall service all forty-four (44) medical centers in the Service Area Office ("SAO") Central Region. See RFP § II at 10.

25. Manus is a service disabled veteran-owned small business ("SDVOSB") as verified through the VA's Center for Verification & Evaluation. See www.vip.vetbiz.gov.

26. Another intended offeror, Geo-Med, LLC, is also a service disabled veteran-owned small business. The RFP is not set-aside for small businesses nor SDVOs

in any way.⁵

C. The RFP Presents an Unresolved OCI

27. As discussed above Cardinal Health 200 and Kreisers are MSPVs supplying their own custom packs to VAMCs with SAO Central as well as distributor the custom packs of their competitors to VAMCs within SACO Central. Both firms have indicated an intention to submit an offer response to the RFP.

28. That leads to a clear potential for Cardinal Health to be serving the VA in two separate and conflicting roles in this procurement. They will serve as suppliers of the custom surgical packs and as medical surgical prime vendors serving as support contractors to or agents of the VA for the distribution of the medical surgical supplies.

29. It is clear as a matter of law that to the extent that contractors such as Cardinal Health and Kreisers have special information or knowledge obtained by virtue of their role as a Government support contractor, the Government has an affirmative obligation under FAR 9.5 to assess and address the organizational conflict of interest that arises from situation. See 48 CFR § 9.504. Failure to reasonably discharge this affirmative obligation is grounds for a sustained protest.

30. Currently, Cardinal Health serves as the MSPV for VA VISNs 9, 10, 11, 12, 15 & 16, or six of the seven VISNs covered by this procurement. Kreisers is the MSPV for the remaining

⁵ Manus currently supplies custom packs to all VA facilities located in the VA's Veterans Integrated Service Network (VISN) 19 by virtue of a SDVOSB procurement awarded by that VISN in 2013. In addition, Manus currently supplies custom packs to two VA facilities, Detroit & Little Rock, covered by this procurement. Geo-Med has also received a number of contract awards from the VA for custom packs, including six VAMCs, (Lexington, KY, Memphis, TN, Huntington, WV, Robley Rex VAMC, James Quillen, VAMC and Nashville, TN) located in SAO Central. Upon information and belief, other SDVOSB firms interested in and capable of competing for this procurement include Marathon Medical.

VISN, VISN 23. In its role as the MSPVs for all of SAO Central both Cardinal Health and Kreisers routinely stock, delivery and process invoices for the product of the incumbent surgical pack providers.

31. That in and of itself constitutes access to proprietary information regarding these competitor's products, as both Cardinal Health and Kreisers knows the precise content of the surgical packs of their competitors, the prices charged for the competitor's products and even the sources of supply that its competitors rely on to stock their surgical packs. Given that reality, the contracting officer must comply with 48 CFR § 9.504 and assess and address this clear potential OCI before proceeding with this procurement.

32. The VA's National Acquisition Center ("NAC"), which awarded the current prime vendor contracts, and which manages and administers the VA's Federal Supply Schedule ("FSS") program, has ruled emphatically that the VA's prime vendors are agents of the Government in distributing products through the prime vendor program.

33. As a result, suppliers whose products are distributed through the Prime Vendor program are obligated to pay the FSS Industrial Funding Fee on all FSS items distributed through the prime vendors, as opposed to the prime vendors paying these fees. Also, the VA NAC has emphatically held that supplier sales to VA end users through the prime vendor program constitute government sales transactions and may not be treated or viewed as commercial sales transaction.

34. These facts further give rise to a "biased ground rules" OCI. There is a clear perception that Cardinal Health and Kreisers have been in a position to influence the term of the RFP, and certainly the requirement that the successful awardee be able to meet with all VAMCs within SAO Central within 30 days of award and resolve questions regarding the content of all surgical packs to be delivered to those VAMCs unduly favors those few competitors that are in contact on a

regular basis with these medical centers regarding the requirements for all of their surgical packs – i.e., the prime vendors. This requirement should be either deleted or significantly relaxed to avoid such blatant “ground rules” favoritism.

D. The Prior Protest to the GAO

35. The Solicitation was issued on August 3, 2015 with an initial due date for proposals of September 2, 2015.⁶ Via Amendment 0005 the closing date for proposal submission was extended to October 14, 2015.

36. On or about October 9, 2015, Manus protested the overly restrictive terms of the RFP, the lack of set aside of the procurement for SDVOs, the improper bundling of the Government’s requirements, and the unresolved OCI to the Government Accountability Office (“GAO”). The Protest was docketed as Manus Medical, Inc., B-412331.

37. On or about January 21, 2016, the GAO denied Manus’s protest, the GAO’s decision is covered by a protective order and has not been publically released.

38. By letter, dated January 22, 2016, the VA notified Manus that it was excluded from the competitive range for the procurement.

39. By letter, dated January 26, 2016, Manus was informed by the contracting officer that it was eliminated from the procurement because the Government believed that the improperly bundled requirements were too large and complex for a small business like Manus to adequately perform and support the Government’s requirements. Therefore, Manus’s allegations concerning the improper bundling and the RFP being written to favor the large business MSPVs was proven by the agency’s subsequent action in eliminating Manus from the competition.

⁶ The services required under the Solicitation were previously the subject of a prior procurement Solicitation No. VA240C-14-R-0008 which was cancelled by the Government.

COUNT I
(Violation of FAR 1.102 & 1.102-2(c))

40. Manus incorporates by reference the allegations set forth above in paragraphs 1 through 39.

41. FAR 1.102 requires Contracting Officers to “[c]onduct business with integrity, fairness, and openness.”

42. FAR 1.102-2(c) requires the Government to “use sound business judgment, and comply with applicable laws in dealing with contractors and prospective contractors” and to treat all contractors and prospective contractors “fairly and impartially.”

43. As described above the VA’s actions in drafting the RFP to benefit MSPVs by bundling the requirements, not setting aside the procurement for SDVOs, failing to resolve the clear OC maintained by the current MSPVs, and removing Manus from the competitive range were the result of the VA’s lack of good faith toward and bias against small businesses suppliers such as Manus, and were not based upon an open, fair and impartial review of Manus’s capabilities or the needs of the Government.

44. The VA’s actions described above were the result of the Agency’s desire to benefit the MSPVs and ensure that the contract was awarded to an MSPV and not a small business like Manus. As such the VA’s actions, were not based upon an open, fair and impartial assessment of Manus’s capabilities or the Government’s legitimate needs.

45. The Agency’s decision to conduct such a biased procurement and remove Manus from the competitive range were motivated by a lack of good faith and bias against Manus and was not based upon an open, fair, and impartial review of Manus’s offer or the VA’s proper consideration and assessment of its needs.

46. Manus has been and will be directly harmed by the VA's failure to evaluate its Proposal fairly and impartially and to conduct its business with integrity, fairness, and openness as required FAR 1.102 and 1.102-2(c).

COUNT II
(Arbitrary and Capricious Agency Action)

47. Manus incorporates by reference the allegations set forth above in paragraphs 1 through 46.

48. As described above the VA's actions in VA's actions in drafting the RFP to benefit MSPVs, by bundling the requirements, not setting aside the procurement for SDVOs, failing to resolve the clear OCI, and removing Manus from the competitive range were arbitrary and capricious and are not in conformance with federal procurement law or regulation.

49. Manus has been and will be directly harmed by the VA's actions as described above.

COUNT III
(Breach of Duty of Good Faith and Fair Dealing)

50. Manus incorporates by reference the allegations set forth above in paragraphs 1 through 49.

51. The VA has breached the duty of good faith, fair dealing, and honest consideration that the VA entered into with Manus when it engaged in the above described actions to wit in drafting the RFP to benefit MSPVs by bundling the requirements, not setting aside the procurement for SDVOs, failing to resolve the clear OCI, and removing Manus from the competitive range were the result of the VA's lack of good faith and bias against Manus, and were not based upon an open, fair and impartial review of Manus's proposal and the Government's needs.

52. Manus has been harmed by the VA's breach of the duty of good faith and fair dealing.

RELIEF REQUESTED

WHEREFORE Plaintiff, Manus respectfully requests that the Court enter judgment in favor of the Plaintiff against the United States and further requests the following relief:

1. That the Court enjoin the Government from awarding or beginning performance of any contract awarded under the RFP as currently drafted.
2. That the Court enjoin the Government from awarding or beginning performance of the RFP as written without the required set aside, the terms benefiting MSPV offerors, and without resolving the clear organizational conflict of interest were arbitrary and capricious.
3. That the Court order the VA revise the RFP to make it set aside for Service Disabled Veteran Owned Small Businesses, not geared to an award to offerors who are MSPVs, and that the Government mitigate the organizational conflict of interest.
4. That the Court order that Manus be returned to the competitive range and be considered for award under the RFP; and
5. The Court award Manus its reasonable costs and attorneys' fees, and such further legal and equitable relief that the Court deems appropriate.

Respectfully submitted,

Dated: February 5, 2016

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